

## REMARKS

The fee for a three-month extension of time and any other fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 02-1818. If a Petition for extension of time is needed, this paper is to be considered such Petition. A Supplemental Information Disclosure Statement and a Petition under 37 C.F.R. §1.48(b) to Correct Inventorship accompany this response.

Claims 1-25, 27-35, 62-70, 72-78 and 82 are pending. Claims 26, 36-61 and 71, directed to non-elected subject matter, are cancelled without prejudice or disclaimer. Applicant reserves the right to file divisional applications to non-elected subject matter and continuing applications to any cancelled or unclaimed subject matter. Claims 72-74 are retained for possible joinder. Claims 69 and 75-77, which are directed to non-elected subject matter, are retained for possible joinder if claim 1 is deemed allowable.

Claims 1, 2, 19, 21-24, 28, 29, 62 and 70 are amended. Claims 1 and 2 are amended to recite compounds of formula II, deleting substituents that do not appear in formula II or the definitions of its substituents. Claims 1 and 2 also are amended to separate the definitions for substituents R<sup>1</sup> and R<sup>2</sup>. Claims 1 and 2, 21-23, 28 and 29 are amended to delete hydrogen as a selection for substituent R<sup>9</sup>. Claims 1 and 2 also are amended for clarity to move the definition of substituents R<sup>10</sup> to appear after the definition of substituents R<sup>9</sup>. Claims 19, 21 and 24 are amended to correct typographical errors. Claim 62 is amended to delete the recitation "prodrug." Claim 70 is amended to depend from claim 69. No new matter is added.

### **I. Change in Inventorship**

Applicant respectfully requests correction of inventorship pursuant to 37 C.F.R. §1.48(b). The accompanying Petition pursuant to 37 C.F.R. §1.48(b) seeks to delete E. Adam KALLEL, Jyun-Hung CHEN, Daniel A. RUPPAR, Bijan PEDRAM and Todd MILLER as inventors of the above-captioned application. This change in inventorship is necessitated by cancellation of subject matter and claims directed to non-elected subject matter.

### **II. Withdrawal of the Previous Restriction Requirement**

Applicant acknowledges the withdrawal of the previous requirement for restriction in view of the change in the Examiner prosecuting this application. Applicant also acknowledges that the previously withdrawn claims are rejoined.

### **III. Traverse of the Restriction Requirement**

The new Restriction Requirement sets forth seventy-eight (78) groups as follows:

- Groups 1-3: Claims 1-68, 78 and 82, directed to compounds of formula II where Z is CR<sup>A</sup>R<sup>B</sup> and n is 0 (Group 1), n is 1 (Group 2) or n is 2 (Group 3);
- Group 4: Claims 1-68, 78 and 82, directed to compounds of formula I;
- Group 5: Claims 1-68, 78 and 82, directed to compounds of formula III;
- Group 6: Claims 1-68, 78 and 82, directed to compounds of formula VI;
- Groups 7-9: Claims 1-68, 78 and 82, directed to compounds of formula IV where Z is CR<sup>A</sup>R<sup>B</sup> and n is 0 (Group 7), n is 1 (Group 8) or n is 2 (Group 9);
- Groups 10-12: Claims 1-68, 78 and 82, directed to compounds of formula II where Z is O and n is 0 (Group 10), n is 1 (Group 11) or n is 2 (Group 12);
- Groups 13-15: Claims 1-68, 78 and 82, directed to compounds of formula IV where Z is O and n is 0 (Group 13), n is 1 (Group 14) or n is 2 (Group 15);
- Groups 16-18: Claims 1-68, 78 and 82, directed to compounds of formula II where Z is S and n is 0 (Group 16), n is 1 (Group 17) or n is 2 (Group 18);
- Groups 19-21: Claims 1-68, 78 and 82, directed to compounds of formula IV where Z is S and n is 0 (Group 19), n is 1 (Group 20) or n is 2 (Group 21);
- Groups 22-24: Claims 1-68, 78 and 82, directed to compounds of formula II where Z is NR<sup>D</sup> and n is 0 (Group 22), n is 1 (Group 23) or n is 2 (Group 24);
- Groups 25-27: Claims 1-68, 78 and 82, directed to compounds of formula IV where Z is NR<sup>D</sup> and n is 0 (Group 25), n is 1 (Group 26) or n is 2 (Group 27);
- Groups 28-30: Claims 1-68, 78 and 82, directed to compounds of formula V where Z is CR<sup>A</sup>R<sup>B</sup> and n is 0 (Group 28), n is 1 (Group 29) or n is 2 (Group 30);
- Groups 31-33: Claims 1-68, 78 and 82, directed to compounds of formula V where Z is O and n is 0 (Group 31), n is 1 (Group 32) or n is 2 (Group 33);
- Groups 34-36: Claims 1-68, 78 and 82, directed to compounds of formula V where Z is S and n is 0 (Group 34), n is 1 (Group 35) or n is 2 (Group 36);
- Groups 37-39: Claims 1-68, 78 and 82, directed to compounds of formula V where Z is NR<sup>D</sup> and n is 0 (Group 37), n is 1 (Group 38) or n is 2 (Group 39); and
- Groups 40-78: Claims 69 and 71-77, directed to pharmaceutical methods of using compounds of Groups 1-39, respectively (*i.e.*, Group 78 corresponds to methods of using compounds of Group 39).

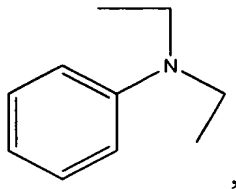
The Examiner, recognizing that the rules of unity of invention under PCT Rule 13.1 apply to the instant case, urges that there is a lack of unity because the 78 groups allegedly do not relate to a single inventive concept, stating that the shared structural feature is an aryl ring substituted in the para-position by a nitrogen-containing substituent, and that this structure is known in the art, citing diethylaniline, which the Examiner states is commercially available as CAS 91-66-7, and thus cannot serve as a special technical feature.

#### ANALYSIS

Reconsideration of the Requirement respectfully is requested in view of the amendments herein and the following remarks.

### 1. Technical Feature is Novel over the Cited Art

The claims are amended to recite compounds of generic formula II. The structure of compounds of formula II is novel over the cited art, diethylaniline, which has the structure:



rendering generic formula II a novel technical feature shared among all claims. Therefore, all pending claims are unified.

It respectfully is submitted that the restriction requirement requiring election of a species of compound of formula II is not correct because it does not identify linking claims. In any Restriction Requirement, linking claims must be identified and examined with the elected group. Applicant has provisionally elected compounds of Group 1, which are compounds of formula II where Z is CR<sup>A</sup>R<sup>B</sup> and n is 0. All pending claims, 1-25, 27-35, 62-70, 72-78 and 82, encompass the elected compounds, and, thus, are generic to the elected compounds. As stated in MPEP §809.03, genus claims are linking claims. Pursuant to MPEP §809, when claims linking more than one group are found, the Restriction Requirement must be conditioned on:

- 1) specifying the linking claims; and
- 2) examining the linking claims with the elected group.

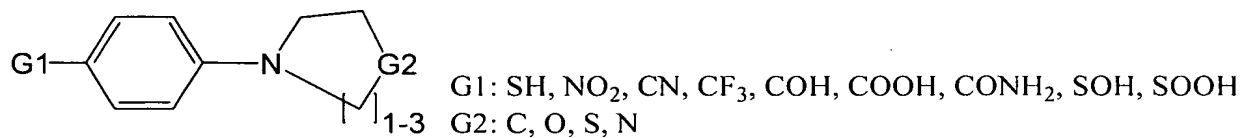
The linking claims must be examined with the elected group; if the linking claims are deemed allowable, then the restriction requirement must be withdrawn and all claims directed to non-elected subject matter that depends from or includes all the limitations of the linking claims must be rejoined. Therefore, the requirement as set forth contains errors as it does not identify claims 1-25, 27-35, 62-70, 72-78 and 82 as linking claims. These claims must be so identified and examined with the elected subject matter.

In this instance, all pending claims are linking claims, and, thus, must be examined with the elected subject matter of Group 1. Similarly for all of groups 1-3, 10-12, 16-18, and 22-24, all claims are linking claims, thus, effectively, rendering the requirement for restriction into these 12 groups a requirement for election of species. Since all claims of groups 2 and 3, and all claims of groups 10-12, and all claims of groups 16-18, and all claims of groups 22-24 include the same novel technical feature as the claims in group 1, the claims of groups 2, 3, 10-12, 16-18, and 22-24 should be joined with the claims of group 1. Claims

1-25, 27-35, 62-70, 72-74 and 82 should be examined as a single group. Therefore, withdrawal of the restriction requirement as between group 1 and each of groups 2, 3, 10-12, 16-18, and 22-24 respectfully is requested.

## 2. No Burden

The Examiner is reminded that if the search and examination of all the claims in an application can be made without serious burden, the Examiner must examine the claims on the merits, even though they may include claims to independent or distinct inventions. In this instance, Applicant respectfully submits that there is no serious burden on the Examiner to search compounds of generic formula II in this application. An STN Express search using a well designed query that encompass all compounds of formula II and includes the limitations recited in the claims could be used for structure searching. For example, the general query:



was tested on STN Express, and because the STN software allows any substitution where chemically permitted (*e.g.*, at all hydrogen locations), it would be expected that a search using this general query would identify related art. A preliminary search using this query was performed and resulted in full file projections from STN that both online and batch processing would run to completion. Since the substituents of formula II as claimed include limitations not included in the above query, a more specific search query incorporating these limitations also would be expected to run to completion, since the addition of more specific limitations in the structure query would further limit the scope of the search, and thus the query would elicit fewer projected answers from the system. Hence, a search of compounds of generic formula II as claimed would not be burdensome.

## 3. Requirement as Set Forth is Not Comprehensive

In addition, it respectfully is submitted that the requirement is improperly set forth because it is not comprehensive and does not afford Applicant the opportunity to prosecute the full scope of the claimed subject matter.

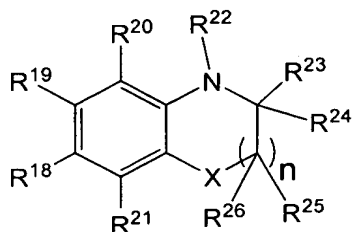
### a. Claim 70

The Requirement is not comprehensive because claim 70 is not included in any group. Claim 70 is a method claim and depends from claim 69. As set forth, claims 69 and 71-77 are restricted amongst Groups 40-78. Claim 70 should be joined with groups that include

claim 69, from which claim 70 depends. Accordingly, the restriction requirement should be restated so that Groups 41-78 include claims 69-77.

**b. Groups 28 - 39**

In addition, Groups 28 through 39, which are directed to compounds of formula V, are not correct and do not comprehensively cover the claimed subject matter. Groups 28 through 39 are divided based on substituents n and Z. Formula V has the following structure:



There is no substituent Z in formula V. It appears that the Office Action should have recited substituent X instead of substituent Z for Groups 28 through 39. Applicant respectfully submits that, even if the recitation "Z" is replaced with "X" in Groups 28 through 39, the Action has not made any provision for electing compounds of formula V where X is a bond. Thus, the restriction requirement as set forth is not correct. Appropriate correction of the requirement for restriction to correct the identified errors and to include Groups directed to compounds of formula V where X is a bond respectfully is requested.

**4. Product and Process of Use Claims - 37 CFR § 1.475**

It also respectfully is submitted that the Restriction Requirement as set forth improperly restricts all process claims from the product claims. This application is a national stage application. Under 37 CFR § 1.475(b)(2), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to a product and a process of use of the product. Applicant is entitled to prosecute claims to a product and a process of use of the product in this national stage application. Claims 72-74, directed to a method for treating a patient having a condition susceptible to treatment with an androgen receptor modulator, the method including administering to the patient a pharmaceutical agent comprising a compound of claim 1, currently are restricted to Groups 40-42, 49-51, 55-57 and 61-63. Claims 72-74 should be examined with the product claims of Groups 1-3, 10-12, 16-18 and 22-24 in this national stage application. Thus, reconsideration of the restriction requirement and joinder of claims 72-74 of Groups 40-42, 49-51, 55-57 and 61-63 with claims 1-68, 78 and 82 of Groups 1-3, 10-12, 16-18 and 22-24 respectfully are requested.

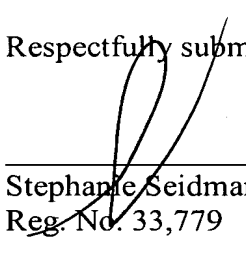
### **5. Correction of the Requirement Respectfully is Requested**

Therefore, in view of the above, correction of the Restriction Requirement as set forth respectfully is requested. Applicant, however, is interested in advancing prosecution, and would like to pursue the claims as amended herein. Withdrawal of the Requirement for Restriction as between group 1 and each of groups 2, 3, 10-12, 16-18, and 22-24, joinder of claims 72-74 of Groups 40-42, 49-51, 55-57 and 61-63 with claims 1-68, 78 and 82 of Groups 1-3, 10-12, 16-18 and 22-24, treatment of the elected group as an election of species, and examination of all linking claims (*i.e.* all pending claims, including claim 1) would achieve this result.

\* \* \*

In view of the provisional election, amendments and remarks herein, reconsideration and withdrawal of the requirement for restriction, examination of all claims on the merits and allowance respectfully are requested.

Respectfully submitted,

  
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